

REMARKS

This Amendment is made to the Office Action dated January 24, 2008. Claims 1-20 are currently pending. Claims 5, 6 and 11 were previously withdrawn in response to an election of species requirement. By this Amendment, claims 1, 8, 15 and 18 have been amended. The amendments to claims 1, 8, 15 and 18 were not made to distinguish the presently claimed invention over the prior art, but rather, to more clearly define the presently claimed invention. Claims 3, 5 and 6 have been canceled without prejudice and claim 4 has been amended to depend from claim 1. New claims 21-23 are being presented. Applicants respectfully request reconsideration of the pending claims in view of the remarks presented below.

Applicants thank the Examiner for allowing Applicants the opportunity to address certain language found in the specification and claims which may have lead to confusion in understanding the structure of the particular species disclosed in FIGS. 12A-D. First, Applicants respectfully point out that the torque device consists of the handle which is directly mountable on the guide wire, means associated with the handle for locking the handle directly on the guide wire (for example, the cap 264) to allow the user to manipulate and rotate the guide wire, and a side port adapted to receive the proximal end of the sheath to shear the sheath from the guide wire through retraction of the sheath through the side port. Claim 1 includes the further recitation of an extension arm extending from the handle which includes a distal end having an opening adapted to receive both the guide wire and the sheath, the end of the extension arm being disposed longitudinally away from the side port. Applicants have amended the specification and claims to indicate that the handle portion of the torque device shown in FIGS. 12A-D is directly mounted to the guide wire and that the distal end of the extension arm 284 includes an opening 285 which receives both the sheath and guide wire. Applicants believe that these changes should address and correct any ambiguities previously found in the pending application.

Claims 8-10 and 12-14 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,228,062 to Howell, et al. (the "Howell patent"). Applicants strongly disagree with the Examiner's position that the Howell patent shows a torque device used to rotate or "torque" a guide wire to steer the guide wire, for example, in the vasculature of a patient. The Howell patent is merely directed to a sheath lock 10 used to split a sheath 36 which extends co-axially over a catheter 14 that is to be placed in the vascular system of a patient. The sheath lock 10 is used with a splittable sheath 36 which is designed to cover a catheter 14 that is being advanced into the vascular system of a patient. The sheath lock 10 is designed to maintain the proximal portion of the catheter 14 sterile by maintaining the sheath 36 co-axially disposed over the proximal portion as the catheter 14 is advanced distally into the patient.

Applicants maintain that the component (needle 24 and wire) identified by the Examiner as a guide wire in the Howell patent is not a guide wire and does not function as a guide wire as this term is known in the medical field. Rather, it is simply a removable needle attached to a wire (not shown) used to insert the catheter 14 into the patient. In use, the wire and needle 24 remain disposed within the lumen of the catheter 14 until the catheter 14 is inserted in the patient. In this regard, the wire which is attached to the needle 24 must be extremely stiff to allow the needle 24 to puncture the skin and body vessel to advance the catheter 14 into the patient. The Howell patent specifically states that the wire and needle 24 are removed from the patient immediately after the catheter 14 has been placed in the patient. The Howell patent reads as follows:

In operation, the wings 32 of the catheter inserter 16 are pinched together. This places sufficient force on the catheter 14 and needle 24 to hold them in place during venipuncture. Once blood vessel penetration is made, the distal end 18 of the catheter 14 is also inserted into the subject blood vessel. At this point, the needle 24 can be withdrawn by pulling on the handle 28 at the proximal end of the device. (Column 4, lines 16-22)

The needle 24, then, merely provides a point for puncturing the skin and blood vessel to allow the catheter 14 to be inserted into the vascular system of the patient. The wire only

acts as a stiffener for achieving the puncture. Thus, the wire and needle 24 of the Howell device cannot be reasonably construed as a conventional guide wire.

In the context of the present invention, the term "guide wire" is properly construed to mean an elongate component that can be used in combination with a number of medical devices, such as balloon catheters, atherectomy devices, filtering devices, just to name a few. The guide wire is generally used with the medical device to allow to be tracked along the guide wire from its free proximal end towards its end position within the patient's body, such that the guide wire acts as a guide for the positioning of the device. This construction of the term "guide wire" is consistent with the meaning understood by those skilled in the art. In general, guide wires are used to find and secure a pathway through the artery and the stenotic lesion. They pass well into the channel and act as a guide to the subsequent passage of therapeutic devices. Moreover, a conventional guide wire does not have a sharp distal tip used for puncturing the body vessel. Simply put, the Howell patent fails to disclose the guide wire as the term is known to one skilled in the art.

Moreover, claim 8 recites that the side port is adapted to receive the proximal end of the sheath to remove the sheath from the guide wire through proximal retraction of the sheath through this side port. The Howell device is not designed to split from proximal retraction of the sheath 36, but rather, uses distal motion of the sheath 36 which also moves the catheter 14 distally into the patient. The Howell patent describes this distal motion as follows:

As illustrated in FIG. 2, the catheter distal end 18 is advanced into the patient's blood vessel (shown by Arrow A) by pulling on the sheath distal end 40 (shown by Arrow B). As the sheath 36 passes through the sheath lock 10, it is split and removed from around the catheter 14. In this manner the catheter 14 can be inserted into a patient in a controlled and sterile manner. (Column 3, lines 52-58).

The Howell patent further states:

The catheter 14 can be advanced into the blood vessel. This occurs by pulling the sheath distal end 40 as shown in FIG. 2. As the sheath 36 moves **distally**, the catheter 14 also moves **distally** into the blood vessel. At the same time, the sheath

36 is split and removed from around the catheter 14. (Column 4, lines 26-29, emphasis added)

This particular arrangement of components in the Howell device simply does not meet the structure recited in the claims. However, in order to expedite allowance of the present application, Applicants have amended claim 8 to state that the means associated with the handle locks the guide wire within the lumen of the handle. In the Howell patent, since the sheath lock 10 does not function as a torque device, the wire and needle 24 remain disposed within the lumen of the catheter 14 in order to allow the needle 24 and wire to be removed after the needle 24 punctures the skin and blood vessel of the patient. Therefore, the sheath lock 10 does not directly contact and hold the wire or needle 24 during usage. For at least these reasons, the Howell patent does not anticipate the claims at issue. Applicants respectfully request the Examiner to withdraw the Howell patent as an anticipatory reference.

Claims 1-4, 7 and 15-20 were rejected under 35 U.S.C. § 103 as being unpatentable over FPD FR 2580504 to Pieronne (the "Pieronne reference") in view of the Howell patent. Applicants strongly disagree with the Examiner's position. Claim 1 requires the filter assembly to include a self-expanding frame movable between an unexpanded position and an expanded position. The filter assembly disclosed in the Pieronne reference appears to use an inflatable balloon 8 to expand the filter. Thus, it lacks the self-expanding frame recited in claim 1. Additionally, claims 1 and 15 recite that the torque device is directly mountable to the guide wire. Even assuming *arguendo* that the Howell patent discloses a torque device, the placement of the sheath lock 10 on the guide wire of the Pieronne reference would not allow the sheath 16 to be removed due to the presence of the filter catheter 15. Thus, the combination of the Pieronne reference with the Howell patent would not create the structure recited in the claims at issue. Applicants respectfully request the Examiner to withdraw the obviousness rejections of claims 1-4, 7 and 15-20.

As mentioned above, the Howell patent teaches the use of a sheath lock 10 with a splittable sheath 36 designed to cover and help advance a catheter 14 that is being

introduced into the vascular system of a patient. The sheath lock 10 is designed to maintain the proximal portion of the catheter 14 sterile by maintaining the sheath 36 co-axially disposed over the proximal portion as the catheter is advanced distally into the patient. Applicants believes that the combination of the Pieronne reference with the Howell patent would actually create a catheter system in which a split seam sheath 36 would be placed over the Pieronne sheath 16 to protect the proximal portion of the Pieronne sheath 16 from becoming unsterile. In this regard, the sheath lock 10 would maintain the outer sheath 36 disposed over sheath 16 of Pieronne, but would allow the distal movement of the sheath 36 to move the sheath/guide wire of Pieronne into the patient. In accordance with the teachings of the Howell patent, the outer sheath 36 would be split by the sheath lock 10 as the distal end of the sheath 36 is moved distally. The sheath lock 10 would thus perform its function of both splitting the outer sheath 36 and locking the sheath 36 to the Pieronne sheath 16 to prevent the proximal portion of the sheath 16 from becoming "uncovered" and possibly contaminated prior to insertion into the patient. For this additional reason, Applicants respectfully request the Examiner to withdraw the obviousness rejection based on the combination of the Pieronne reference with the Howell patent.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Please charge any fees payable in connection with this response to Deposit
Account No. 06-2425.

Respectfully submitted,

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